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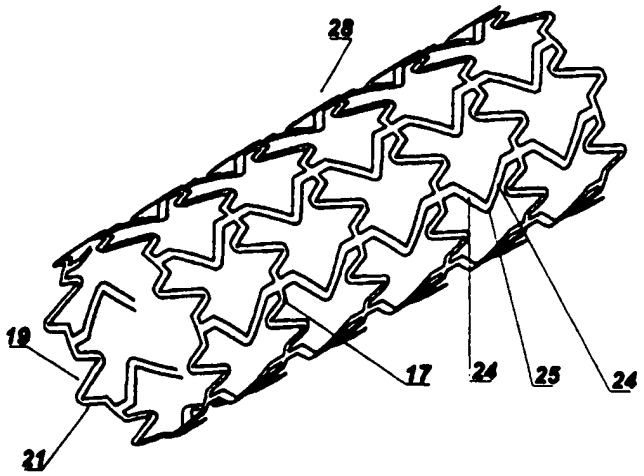

(57) Abstract

The optimum stent mechanical model is designed for radical recovery of an arterial lumen and therefore for blood flow normalization. The stent (10) comprises a series of circular bands (17) disposed over a common longitudinal axis, each of the bands (17) consisting of diametrical deformation compensators (CDD) (19) and undeformable portions of circular surface (20). The adjacent circular bands (17) are connected by longitudinal deformation compensators (CLD) (19), disposed in an intermediate zone between the circular bands (17). The CDDs (16) and CLDs (23) are not kinematically connected in the optimum mechanical stent model. This means that the coronary artery dynamical mechanical forces and deformation will not be transferred from CLD (23) to CDD (19), and so the natural arterial dynamics will not be affected. Designing a given stent model, tailored to specific clinical demands, requires calculation of the dependencies for the indicated CDDs (19) and CLDs (23). In accordance with specific clinical requirements several different cardiovascular expandable stent models are claimed.

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The Optimum expandable stent mechanical model and its application

Field and background of the invention

The invention is an expandable cardiovascular stent, which is intended for radical arterial lumen recovery matching the normal blood flow.

Modern stent implantation technology, into a coronary artery, for example, comprises the following substantial steps:

1. Positioning of the stent over a uninflated balloon of a conducting catheter.

2. Delivery of the stent to a location of a pathological formation within the coronary artery.

3. Expansion of the stent to the desired diameter through hydraulic inflation of the balloon, termination or significant moderation of a pathological formation in the coronary artery, emptying the balloon and withdrawal of the catheter from the coronary artery.

4. Functioning of the implanted stent in the coronary artery.

The first step does not show any specific difficulties for an attending physician. The second step is also rather easily performed with both short and relatively long stents, if the long ones are made of uniform short units and are interconnected by intermediate links of various construction.

During the third step, as the balloon inflates, the freely flexed stent in the artery erects and forms a linear cylinder which is dynamically extending in diameter. The balloon's load on the inward surface of the stent is so large that resistance reaction to the stent expansion, and especially to the straightening of the curved local portion of the artery, may be neglected. Only the balloon's pressure on the stent inward surface is essential in the third step, and this pressure is intended to expand the stent till its diameter reaches a required value.

Transition to step 4 is associated with the appearance of the mechanical forces of the

artery acting on the stent in radial direction, as the stent is no longer supported by the balloon. These mechanical forces tend to reduce the stent and to decrease the lumen size of the coronary artery to the pre-operational width. Said mechanical forces exert a bending influence on the stent tending to give it the curvilinear shape of a natural coronary artery curvature.

The action of the aforementioned coronary artery radial mechanical forces on the stent takes place all the way through the implantation time, changing dynamically in magnitude and direction as well as in character of its intensity distribution. These fluctuations are determined by the dynamics of arterial blood pulsation and heart muscle palpitation, constantly altering the arterial curvature.

The character of the above mentioned dynamics can typically be seen as a cyclic one with temporary changes in amplitude and period. Therefore, the optimum mechanical stent model must have the properties of dynamical compatibility with characteristics of mechanical forces and cyclic displacements of the coronary artery. These properties can be formulated as follows:

A. Maximum resistance of the stent to the coronary artery reduction.

B. Minimum resistance of the stent to the coronary artery longitudinal mechanical compliance.

The "ideal" stent model should not shrink radially while showing no resistance to the continuously changing trajectory of the artery.

The Prior Art

The articulated stent **1** (Fig. 1, 2) comprising at least two "rigid" segments **2** is known. These segments are connected by a set of cells **3**, each having an apex **4**. Upon stent **1** expansion each of the "rigid" segments **2** takes a shape of a cylindrical rhomboidal net **5**. In addition to this the stent **1** contains a flexible connector **6** which includes a set of flexible links. Each link embraces portions of each pair of

adjacent cells 3, having a flexing flat. Upon stent 1 expansion the flexing flat remains flexed (see USA. Patent No.5,449,373, 9/1995).

The flexible connector 6 can be described either as a set of helical (spiral) hinges 7 (Fig. 1), connecting said adjacent "rigid" segments 2, or as a group of several meshed hinges 8 (Fig. 2), each having at least one flexing flat.

The considered stent does not meet the requirements of the optimum mechanical model, first of all, because it does not have a property of maximum resistance to the coronary artery reduction. Upon stent 1 expansion, the "rigid" segments 2 form the cylindrical rhomboidal net 5. As it is well-known, any quadrangle, including a rhomboid, loaded diagonally, is a classic example of an unsteady geometrical figure.

According to the optimum mechanical model conception, the above mentioned "rigid" segments 2 play the role of diametrical deformation compensators (CDDs), which render resistance upon stent expansion with the help of a balloon in the coronary artery. These CDDs also receive dynamical radial mechanical forces of the coronary artery after the stent 1 has achieved patency and the conducting catheter has been withdrawn.

In this construction the flexible connector 6 functions as a longitudinal deformation compensator (CLD), that is intended to counterbalance the bending forces on the stent 1 occurring together with continuous displacements of different coronary artery portions. The binding loci of the flexible connector 6 (CLD) are the apices 4 of the adjacent cells 3 of the "rigid" segments 2. Therefore, upon stent 1 expansion, the forces are transferred, and deformation occurs to both: the "rigid" segments 2 (CDD) and the flexible connector 6 (CLD).

When the coronary artery exerts a bending force on the stent , the "rigid" segments 2 change their geometrical sizes. Since the bending forces are repeated periodically and continuously, the "rigid" segments 2 actually do not function as CDDs.

We will now consider a construction of the flexible connector **6** of the above mentioned stent, as shown in Fig. 1, 2.

Upon longitudinal deformation of the stent **1** the outward surface **9** curve radius is larger than that of the inward surface **10**. The flexible connector **6** (CLD) is intended to balance the difference in lengths of the flexing flats of the surfaces **9** and **10**. However, upon longitudinal deformation of a one-hinged stent **1** (Fig. 1), the hinge **7** does not alter its length at all, and hence does not equalize the changes in the lengths of the previously mentioned flexing flats. Therefore, the flexible connector **6** does not function as a CLD.

The flexible connector **6**, constructed as several (three) meshed hinges **8** (Fig.2), features high compensatory ability against longitudinal deformations. But as the middle hinge of the connected knot in this construction has too many degrees of freedom, its spatial orientation is uncertain. There exists a possibility that this knot would place itself in a coronary artery transversely to the blood flow. Furthermore, according to the patent formula, the flexible connector **6** comprises a set of the mentioned hinges **8**, thus providing a possibility of total occlusion of the coronary artery.

A misleading approach to the development of basic functional elements of the stent construction can be detected through the analysis of the USA, Patent No. 5.514.154, 5/1996 (Fig. 3) as well. Here, to avoid shortening of the gap between the cylindrical elements **11** upon stent expansion, the connector **12** (CLD) is made rigid. Therefore, the same cylinder **11** functions as a CDD and a CLD simultaneously, thus contradicting the very essence of the optimum mechanical model.

Summary of the invention

The purpose of the invention is creation of an optimum cardiovascular mechanical stent model featuring dynamical compatibility with coronary artery forces

characteristics and its cyclic displacements.

This aim is achieved by the fact that a series of circular bands, disposed over a common longitudinal axis, is constructed in the proposed stent mechanical model, each of these bands comprising at least one CDD and one undeformable portion of circular surface. The above mentioned CDD is positioned parallel to the above mentioned longitudinal axis of said series of the circular bands and comprises at least two rods, constructed in the lateral surface of the above mentioned circular band. Said CDD rods are conjugated by a common apex and form a v - like connection. They could also be connected either by a portion of curvilinear surface or by a rod, while their loose ends are either closed by the mentioned undeformable portion of circular surface, or are connected to the adjacent couple of CDD rods. This adjacent pair of CDD rods, that is constructed in the aforementioned lateral surface of the aforementioned circular band, can be either identical or different in shape, relative disposition and geometrical sizes to the original CDD rods.

Apart from this, the proposed mechanical stent model contains at least one CLD, that embraces the aforementioned adjacent circular bands.

Said CLD is positioned into an intermediate zone, between said adjacent circular bands perpendicularly to said longitudinal axis of the stent. The CLD comprises at least two rods that have a common apex and form a v - like connection, or are interconnected either by a portion of curvilinear surface, or by a rod, while their loose ends are closed by said undeformable portions of the circular surface of said adjacent circular bands.

In the stent construction, said CDDs and CLDs can be made either of a whole slotted tube sample or of a standard wire sample. It is preferable to make said CLDs of a biologically compatible thread of temporary activity.

In the proposed mechanical stent model said CDDs and CLDs are not

interconnected kinematically. For this reason, when bending mechanical forces are exerted on the stent, neither forces nor deformation transfer from said CLDs to said CDDs takes place. The stent outward surface generatrix curvature radius along said longitudinal axis is altered by said CLDs only. This fact provides the minimum stent resistance to the coronary artery bending mechanical forces as well as preserves the natural artery curvature, and denotes the essential claim for their dynamic compatibility.

A simultaneous diameter increment along with each circular bands' width decrement, is observed only upon stent expansion in the coronary artery with the help of a balloon. These alterations in geometrical sizes, under the stent deformation of the kind described, concern said CDDs only. As the stent is maximally expanded, each of said circular bands forms a shape, approaching that of an even undeformable closed loop, its diameter being equal to that of the coronary artery inward surface and its width approaching that of said rod of said CDD. Therefore, the stent in general provides the maximum resistance to the reduction of the coronary artery, preserves the natural arterial lumen and, consequently, the normal blood flow. This is another essential claim for their dynamic compatibility.

Therefore, the proposed stent mechanical model, providing maximum resistance to the coronary artery radial forces on the one hand, and minimum resistance to its continuous alterations in spatial position on the other, is the optimum model as it features dynamical compatibility with coronary artery parameters.

Designing a given stent model, tailored to specific clinical requirements, demands calculation of the dependencies for the indicated CDDs and CLDs. Choosing technical characteristics of said stent is then predetermined by the values of the corresponding rigidity and flexibility parameters of the coronary artery.

The proposed optimum mechanical model provides the following:

- calculation of a stent diameter increment upon stent expansion in the coronary artery, the maximum stent diameter being a constant corresponding to that of the inward coronary artery surface;
- practically unalterable stent length upon its expansion in the artery;
- calculation of a stent flexibility at its stretching - compression, having the option of wide regulation of a flexibility degree;
- decrease total mass of the stent proportionally to the coronary artery diameter decrease;
- constructing the stent outward surface generatrix profile in precise correspondence to that of the inward coronary artery surface (stents with cone-like outward surface);
- production of clinical samples 4 - 80 mm in length;
- shape and size regulation of cylinder net cell cross-section, the net being formed upon stent expansion (a possibility of stent implantation into a bifurcating coronary artery);

In addition to this, the constructive features of the proposed stent allow creation of a whole theoretical concept of a cardiovascular stent design independent of the initial sample, used for this purpose (slotted tube, wire, etc.), including the "ideal" model creation. Thus, due to the feature of dynamic compatibility between the stent technical parameters and values of the coronary artery mechanical forces and movements, implantation of the stent, constructed in accordance with the proposed mechanical model, will not only increase the effectiveness of cardiological intraoperational involvement, but also optimize functioning of the stent compared to that of all known clinical analogues.

Brief description of the drawings

The invention is herein described with the help of an example and references to the accompanying drawings, wherein:

Fig. 1 - shows an articulated stent (prior art), its flexible connector being one hinge.

Fig. 2 - shows an articulated stent (prior art), its flexible connector being several meshed hinges.

Fig. 3 - shows an expandable stent with a rigid flexible connector.

Fig. 4 - shows schematically versions of stent circular band construction:

a) as a undeformable closed loop; b) as a combination of a CDD and a undeformable portion of circular surface; c) as a deformable circular surface comprising only CDDs.

Fig. 5 - shows schematically the types of CDD and CLD rod connections:

a) a v - like rod connection; b) a rod connection by a curve surface portion; c) a connection by a rod.

Fig. 6 - shows schematically a curvilinear element, a CDD used for calculation of minimum D_{min} (a) and maximum D_{max} (b) diameters dependencies:

d is the diameter of a circle inscribed into the CDD rod cross-section; l_i is a CDD rod length.

Fig.7 - shows schematically the stent bend along its longitudinal axis upon stretching or compression:

R_1 is the outward stent surface generatrix curvature maximum radius; R_2 is the outward stent surface generatrix curvature minimum radius; R_0 is the outward stent surface generatrix curvature neutral radius; K_1 is a segment occupied by a CDD over an arc with R_1 radius; K_2 is a segment occupied by a CDD over an arc with R_2 radius.

Fig. 8 - shows schematically a construction unit, a CLD, used for calculation of R_2 dependence.

d is a diameter of a circle inscribed into the CLD rod section; l_m is the CLD rod length.

Fig. 9 - shows the optimum mechanical stent model, before expansion (the stent surface evolvent is shown).

Fig. 10 - shows the same as Fig. 9, after the stent expansion.

Fig. 11 - shows the proposed optimum mechanical stent model with expansion bounded by the maximum diameter D_{max}, before expansion.

Fig. 12 - shows the same as Fig. 11, after the stent expansion.

Fig. 13 - shows the optimum mechanical stent model with expansion bounded by the maximum diameter D_{max} and a cone-like surface, before expansion (the stent surface evolvent is shown).

Fig. 14 - shows the same as Fig. 13, after the stent expansion.

Calculating dependencies for the optimum mechanical stent model

On Fig. 4 versions of a stent circular band construction are shown schematically. Fig. 4a shows a undeformable circular band constructed as an even closed loop **13**. When the expanding mechanical forces are applied, such a loop alters its geometric sizes only within the bounds of the elastic deformation of its own material. The value of such a deformation for a metal loop is rather small. For this reason, the loop **13** will restore its original sizes after its expansion.

If a circular cut is made in the undeformable even closed loop **13**, and a curvilinear element **15** is positioned into the cleave, as is shown on Fig. 4b, the curvilinear element **15** will function as a CDD upon expansion due to its bending and expanding ability.

Upon expansion, under the influence of mechanical forces, the curvilinear element **15** (CDD) promotes the circular band **14** diameter increment to a certain limited value. At the same time the degree of the circular band **14** diameter increment upon expansion is proportional to the coefficient **n** - the amount of the used curvilinear elements **15** (CDD), thus being a function of the **n** coefficient.

A circular band with maximum expanding ability is shown on Fig. 4c, the ability provided by the fact that this circular band comprises mostly CDDs (pos. **16**).

Fig. 5 shows schematically various CDD rod connections. A CDD can be

constructed as different combinations of linear or conditionally linear rods, that are merged together either by a v-like connection (Fig. 5 a), or by a curvilinear surface portion (Fig. 5 b), or by a rod (Fig. 5 c).

When all the CDDs, each comprising two rods, are compressed (Fig. 6 a), the minimum stent diameter D_{min} is bounded only by the conducting catheter uninflated balloon outward surface diameter , and can be calculated as follows:

$$D_{min} \approx \frac{2d}{\pi} \cdot n \qquad (1)$$

where **d** is the diameter of a circle inscribed into the CDD rod section; **n** is the CDD amount in the circular band.

When all the CDDs, each comprising two rods are stretched, (Fig. 6 b), the stent maximum diameter D_{max} is calculated as follows:

$$D_{max} = \frac{\sum l_i}{\pi} \cdot n \qquad (2)$$

where l_i is the length of a CDD rod.

The maximum diameter value upon stent expansion is the most important parameter of its technical characteristics. All known clinical analogues, however, have conferred this parameter with only a recommended value, since it was not backed by constructive features and, accordingly, stent mechanical properties.

The proposed optimum mechanical stent model features diameter limitation upon expansion. The criterion of this parameter choice is the value of the coronary artery inward surface diameter D_{ca}.

For a precisely measured stent $D_{ca} \approx D_{max}$ (3)

(where $\mathbf{D_{ca}}$ is the coronary artery inward surface diameter), because for every patient during the intraoperational involvement the coronary artery inward surface diameter is practically constant and can be measured. Therefore, the ratio $\sum l_i \cdot n / \pi$ is also a constant. Therefore, both the amount of CDDs **(n)** and rod

length (l_i) can be varied in the process of specific stent model design in accordance with clinical requirements.

The essential optimum mechanical stent model feature is the fact that upon expansion to the maximum diameter D_{max} every circular band takes a shape approaching that of a round undeformable closed loop with diameter equal to that of the coronary artery inward surface, D_{ca}, and with loop's width approaching that of a CDD rod. This allows to preserve securely the stent diameter value after expansion and decreases the stent's mass due to the more rational geometrical configuration.

The optimum stent mechanical model comprises at least two circular bands separated by an intermediate zone. Respectively, a stent with q circular bands will have (q-1) intermediate zones.

Static and dynamic function differentiation between circular bands and a construction element connecting these bands in the intermediate zone is the basis for the mechanism of dynamical compatibility between the proposed stent model mechanical characteristics and the corresponding coronary artery parameters. Since in its working position (after expansion) a circular band has exclusively a static function of keeping the size of the coronary artery lumen constant, a construction element of the intermediate zone must have a dynamic function, that is kinematic responding to spatial displacements of the coronary artery separate portions. In other words, the coronary artery bending mechanical forces influence on the stent should not be associated with forces and deformation transfer from the flexible construction element of the intermediate zone expanded to the maximum diameter D_{max} to the rigid circular band, this being the essential feature of the proposed invention.

Fig. 7 shows schematically the bend of a stent along a longitudinal axis upon stretching - compression. It can be clearly seen that upon a stent's bend, the length of a k_i segment, occupied by a CDD on an arc of a bigger radius R_i, is larger than

that of a segment k_2, occupied by the same CDD on an arc of a lesser radius R_2. This illustrates the difference in deformation values of the compared segments of the stent diametrical cross-section. That is why the construction element of the intermediate zone is used as a CLD, featuring high compliance upon stretching - compressing.

In the optimum mechanical stent model, a construction element - CLD of the intermediate zone is made similar to CDD (see Fig. 5).

The calculation parameter of the longitudinal mechanical compliance (flexibility) of the stent with said CLDs, each comprising a couple of rods, is the stent outward surface generatrix curve minimum radius R_2 (Fig. 7, 8), for which

$$R_2 = \frac{D_{max} \cdot 2d}{\sum_{m=1} l_m - 2d} \qquad (4)$$

where $\mathbf{D_{max}}$ is the maximum diameter upon stent expansion; **d** is the diameter of the circle, inscribed into CLD rod section, $\mathbf{l_m}$ is a CLD length.

There are two possibilities to improve the stent flexibility, i.e. to decrease a curve radius R_2: either to decrease the numerator in the expression (4) or to increase its denominator. However, the numerator factors $\mathbf{D_{max}}$ and **d** in the expression (4) are constants. Therefore, the stent flexibility alteration parameter according to the expression (4) is the sum of CLD rods' lengths.

Being a function of this sum, the stent longitudinal mechanical compliance (flexibility) maximum value also depends on a possibility of rational positioning of the CLD rods in the intermediate zone between circular bands. For this reason, technologicity should be accounted for when designing the stent.

An additional possibility of the stent flexibility degree regulation is the amount of the CLDs and their spatial disposition in the intermediate zone. A multitude of construction modifications can be proposed here, in each specific case determined

by the corresponding clinical demands.

The curve radius R_2 absolute minimum value can be achieved if the construction element (CLD) of the intermediate zone is made of a biologically compatible thread of temporary activity.

During the stent functioning in the coronary artery, symmetric deformations in both directions take place, while the angle between the CLD rods (see Fig.5) alters periodically from 0 to 180^0. Thus, it is most reasonable to dispose these rods at the angle of about 90^0.

Specific description

Fig. 9 shows the optimum mechanical stent model according to the invention made in a whole slotted tube sample, before expansion.

A series of circular bands **17** is disposed over a common longitudinal axis. The circular band **17** comprises the alternating CDDs (pos. **19**), disposed parallel to the stent **18** longitudinal axis, as well as undeformable portions of circular surface **20**. A CDD (pos. **19**) comprises three rods **21**, conjugated in apices **22** by v-like connections. The rods **21** have different lengths and are made in the lateral surface of the circular band **17**. The loose ends of CDD rods **21** (pos. **19**) are closed by undeformable portions of circular surface **20**.

CLDs (pos. **23**) that embrace the circular bands **17** are disposed in the intermediate zone between the adjacent circular bands **17** perpendicularly to the stent **18** longitudinal axis. A CLD (pos. **23**) comprises two rods **24**, conjugated by a v-like connection at an approximately 90^0 angle in an apex **25**. The rods **24** are equal in length, and are connected by their loose ends to the portions of undeformable circular surface **20** of the adjacent circular bands **17**.

Fig. 10 shows the same stent as Fig.9, expanded to a diameter D less than its maximum diameter D_{max} according to the accepted clinical technology. It is clearly seen on Fig. 10 that only CDDs (pos. **19**) deform and alter their geometrical sizes

upon stent expansion. The CLDs (pos. **23**), joined to the corresponding circular surface **20** undeformable portions of circular bands **17**, are not sensitive to mechanical forces and deformation upon stent expansion. As all CDD (pos. **19**) rods **21** are made identical, the stent **18** preserves its cylindrical shape after expansion.

Fig. 11, 12 show the stent correspondingly before and after expansion, where the CDD (pos. **19**) rods **21** are designed in such a way, that after the stent expansion to the maximum diameter D_{max}, the circular bands **17** take a shape approaching that of a round undeformable closed loop. The outward diameter of such a loop (Fig. 12) corresponds to the coronary artery inward surface diameter D_{ca}, while the loop's width approaches that of the CDD (pos. **19**) rod **21**. Herein, after the circular bands **17** achieve the maximum diameter D_{max}, angular apices **25** of the CLD (pos. **23**) conjugated rods **24** inculcate into a wall of the coronary artery inward surface, thus promoting a better adjoining to its tissue.

The absence of kinematic connection between the CDDs (pos. **19**) of the circular bands **17** and the CLDs (pos. **23**) allows the stent **18** not to alter its length upon expansion to the maximum diameter D_{max}.

A coronary artery recovers its normal hydrodynamic properties after stent expansion. The proposed stent model implanted into the artery does not distort its natural dynamics upon heart muscle palpitations, which creates favourable conditions for the atraumatic process of the stent outward surface connection to the coronary artery tissue and for a more effective stent functioning during a long period.

The proposed stent minimum longitudinal size is determined by a sum of the corresponding longitudinal sizes of two adjacent circular bands **17** and a CLD (pos. **23**).

The proposed stent maximum longitudinal size corresponds to that of the working part of a conducting catheter balloon.

Fig. 13, 14 show a stent surface evolvent in which CDD (pos. **19**) rods' **21** lengths are consecutively decreased in a series of the disposed circular bands **17** from pos. **26** to pos. **27** of the stent **18**, before and after expansion correspondingly.

As a result of this, according to the expression (2) a stent with a cone-like outward surface is formed. Here, it is substantially important that when all the CDD (pos. **19**) rods **21** are in their undeformable, non-working position (before expansion), the stent outward surface is of a regular cylindrical shape. Only after stent **18** expansion to the maximum diameter D_{max} its outward surface takes the required cone-like shape (Fig. 14).

The proposed stent model has still another substantial feature. The diameter of a conditional stent, mounted on a uninflated balloon of a conducting catheter, can be inscribed in the diametrical sizes of a cylindrical net **28** (see Fig. 12) cell, the net **28** being formed after the stent expansion. This is achieved due to the possibility to vary the lengths of rods **21**, **24** of CDDs (pos. **19**) and CLDs (pos. **23**) respectively, which enables stent implantation into a bifurcating coronary artery.

Therefore, the proposed optimum stent mechanical model, featuring functional dynamical compatibility with the coronary artery parameters, is a breakthrough in effectiveness of coronary artery treatment, also enabling an essential increase of cardiovascular stents involvement into the most wide clinical practice.

Industrial applicability

The offered optimum stent mechanical model is a basis for design, production and application of a wide spectrum of cardiovascular samples. The model is recommended for bulk serial and massive production. A preferred mode of the optimum stent mechanical model production is described above. Still, the construction equivalent element can be improved without losing the invention advantages, formulated as follows.

What is claimed is:

The optimum stent mechanical model, comprising

1. a) A series of circular bands disposed over a common longitudinal axis, each comprising at least one diametrical deformation compensator (CDD) and one undeformable portion of circular surface; whereas said CDD is disposed parallel to said longitudinal axis of said series of circular bands and comprises at least two rods made in the lateral surface of said circular band, said rods are connected while their loose ends are closed by a undeformable portion of circular surface made in said lateral surface of said circular band;

b) at least one longitudinal deformation compensator (CLD) which embraces said adjacent circular bands; whereas said CLD is disposed in the intermediate zone between said adjacent circular bands perpendicularly to said longitudinal axis, comprising at least two rods, said rods are connected, their loose ends being closed by said undeformable portions of circular surface of said adjacent circular bands.

2. The optimum stent mechanical model as in claim **1**, wherein said circular band consists of said alternating CDD and said undeformable portions of circular surface, whereas said CDD rods are made identical in shape, relative disposition and geometrical sizes in said lateral surface of said circular band.

3. The optimum stent mechanical model as in claims **1, 2**, wherein said CDD rods are made different in shape, relative disposition and geometrical sizes in said lateral surface of said circular band.

4. The optimum stent mechanical model as in claim **1**, wherein said loose ends of said CDD rods are connected to the loose ends of said adjacent CDDs made in said lateral surface of said circular band.

5. The optimum stent mechanical model as in claims **1, 2, 3, 4**, wherein said CDDs and said CLDs are made in a whole slotted tube sample.

6. The optimum stent mechanical model as in claims **1, 2, 3, 4**, wherein said CDDs and said CLDs are made of a standard wire sample.

7. Optimum stent mechanical model as in claim 1, wherein said CLDs are made of biologically compatible thread of temporary activity.

8. Optimum stent mechanical model as in claims 1, 2, 3, 4, 5, 6, 7 , wherein upon said stent expansion only said CDDs deform and alter their geometrical sizes,

- whereas calculation parameters of said circular band with said CDDs, each of which comprises two rods, are minimum D_{min} and maximum D_{max} diameters of said stent, calculated upon compression and stretching correspondingly of all said CDDs,calculated according to the following formulae:

$$D_{min} = \frac{2d}{\pi} \cdot n \qquad \text{and} \qquad D_{max} = \frac{\sum l_i}{\pi} \cdot n,$$

where **d** is a diameter of the circle inscribed into CDD rod section; **n** is the amount of CDD in a circular band; l_i is CDD rod length, and for a precisely measured stent

$$D_{max} = D_{ca},$$

where D_{ca} is a coronary artery inward surface diameter;

- whereas upon said stent maximum expansion, said circular band takes a shape approaching that of a round undeformable closed loop, equal in its diameter to that of said coronary artery inward surface D_{ca}, with said loop's width approaching that of said CDD rod;

- whereas the length of said rods of said CDD is decreased proportionally to said coronary artery inward surface diameter D_{ca} decrease;

- whereas a profile of said stent outward surface generatrix along said longitudinal axis is made in precise correspondence with the profile of the coronary artery inward surface, and in case of said inward coronary artery surface being conical, said stent outward surface generatrix decline magnitude along said longitudinal axis is regulated by altering the parameters l_i and **n** in the expression

$$D_{max} = \frac{\sum l_i}{\pi} \cdot n$$

9. The optimum stent mechanical model as in claims **1**, **2**, **3**, **4**, **5**, **6**, **7** , wherein upon said stent bending along said longitudinal axis, only said CLDs deform and alter the curve radius of said stent outward surface generatrix;

- whereas a calculation parameter of longitudinal mechanical compliance (flexibility) of said stent with said CLDs, each comprising two said rods, is a minimum curve radius R_2 of said outward surface generatrix of said stent, calculated as follows:

$$R_2 = \frac{D_{max} \cdot 2d}{2} \Big/ \sum_{m=1} l_m - 2d ,$$

where $\mathbf{D_{max}}$ is the maximum diameter upon said stent expansion; **d** is a diameter of the circle inscribed into said CLD rod section; $\mathbf{l_m}$ is a said CLD rod length.

10. Optimum stent mechanical model as in claims **1**, **2**, **3**, **4**, **8**, **9**, wherein upon said stent application to at least one of bifurcating arteries, said CDD and CLD rods' lengths are calculated in such a way that the diameter of a conditional stent, disposed over an uninflated balloon of a conducting catheter, could be inscribed into the cross-section of a cylindrical net cell, said net being formed after said stent expansion.

AMENDED CLAIMS

[received by the International Bureau on 13 June 1997 (13.06.97); original claim 7 amended; remaining claims unchanged (1 page)]

7.Optimum stent mechanical model as in claim 1, wherein said CLDs are made of a biologically compatible tissue with a possibility of filling the said tissue with a regulated dose of medicinal preparations.

8. Optimum stent mechanical model as in claims 1, 2, 3, 4, 5, 6, 7 , wherein upon said stent expansion only said CDDs deform and alter their geometrical sizes,

- whereas calculation parameters of said circular band with said CDDs, each of which comprises two rods, are minimum D_{min} and maximum D_{max} diameters of said stent, calculated upon compression and stretching correspondingly of all said CDDs, calculated according to the following formulae:

$$D_{min} = \frac{2d}{\pi} \cdot n \qquad \text{and} \qquad D_{max} = \frac{\sum l_i}{\pi} \cdot n,$$

where **d** is a diameter of the circle inscribed into CDD rod section; **n** is the amount of CDD in a circular band; l_i is CDD rod length, and for a precisely measured stent

$$D_{max} = D_{ca},$$

where D_{ca} is a coronary artery inward surface diameter;

- whereas upon said stent maximum expansion, said circular band takes a shape approaching that of a round undeformable closed loop, equal in its diameter to that of said coronary artery inward surface D_{ca}, with said loop's width approaching that of said CDD rod;

- whereas the length of said rods of said CDD is decreased proportionally to said coronary artery inward surface diameter D_{ca} decrease;

- whereas a profile of said stent outward surface generatrix along said longitudinal axis is made in precise correspondence with the profile of the coronary artery inward surface, and in case of said inward coronary artery surface being conical, said stent outward surface generatrix decline magnitude along said longitudinal axis is regulated by altering the parameters l_i and **n** in the expressio:

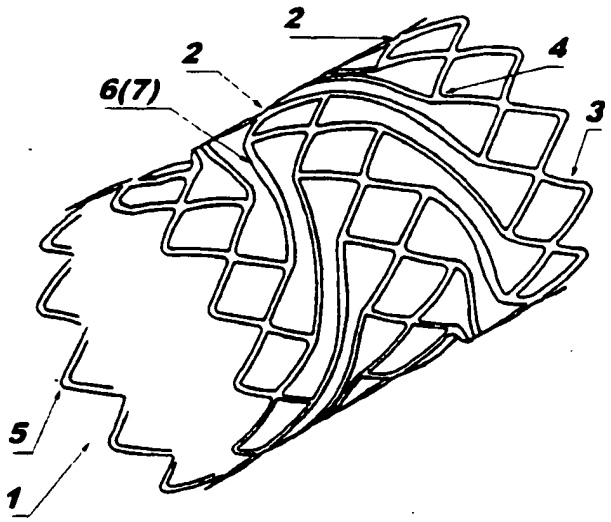


Fig.1

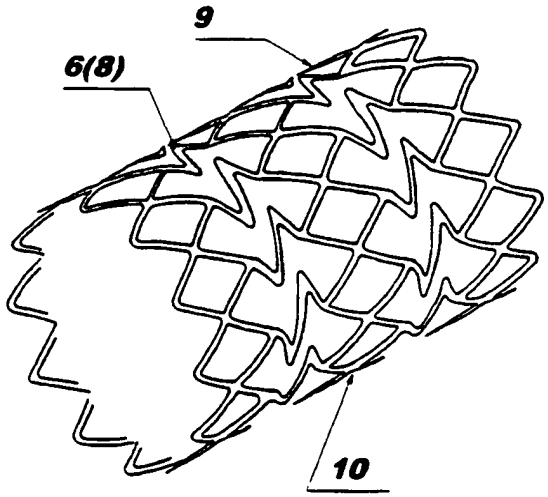


Fig.2

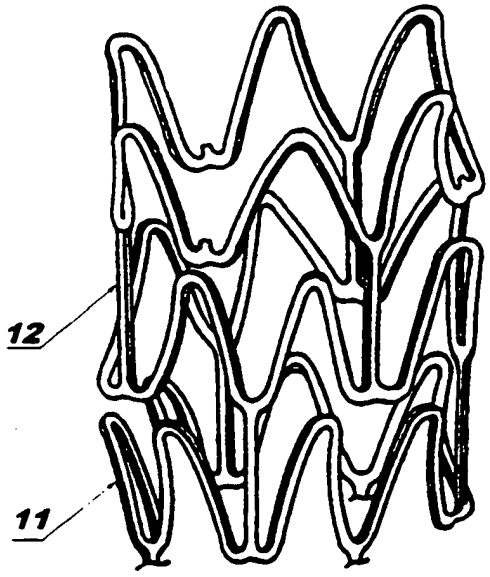


Fig.3

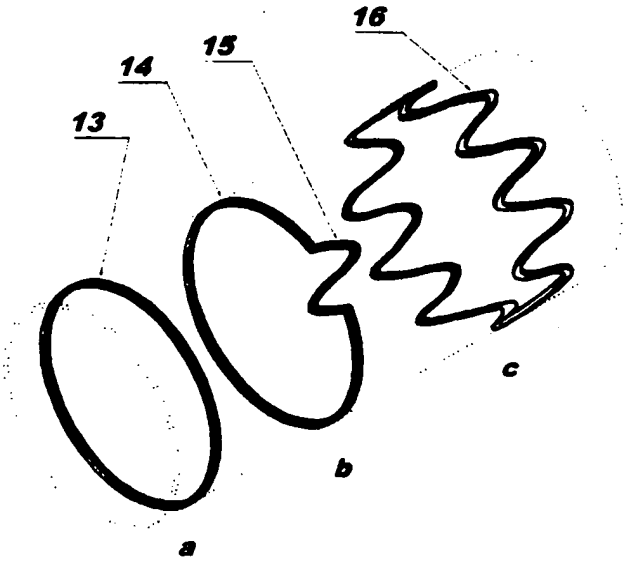


Fig.4

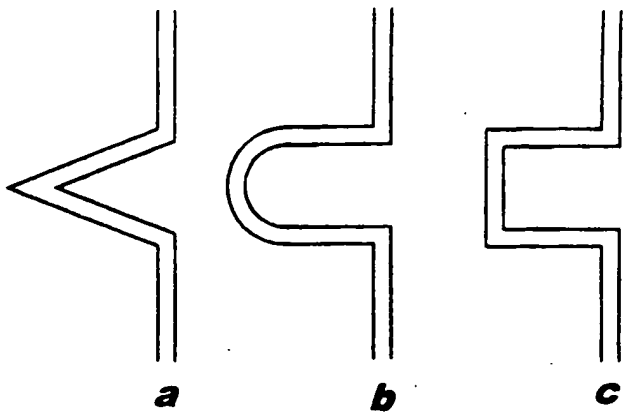
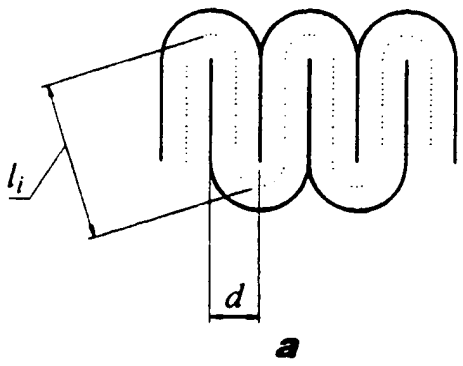


Fig.5



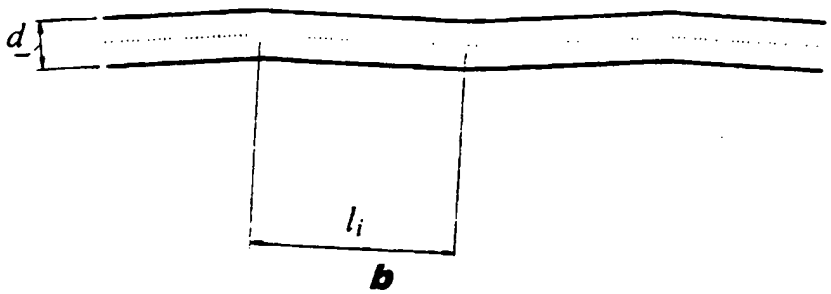


Fig.6

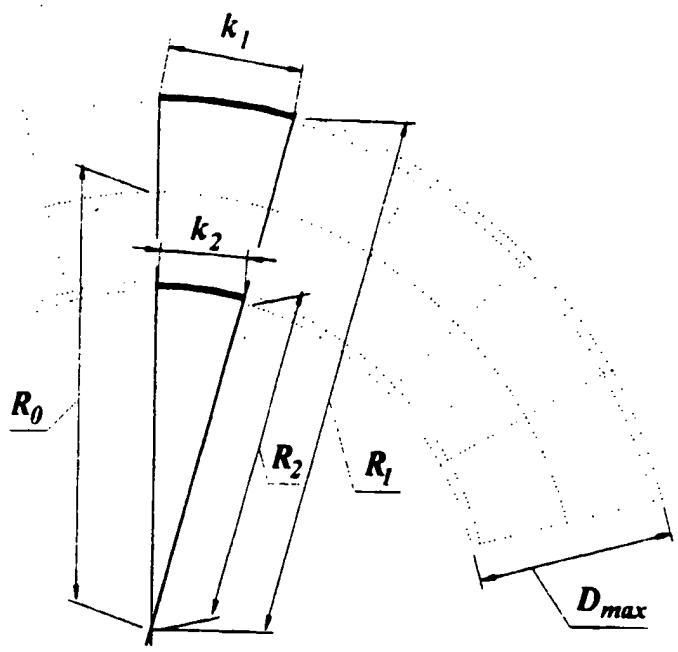


Fig.7

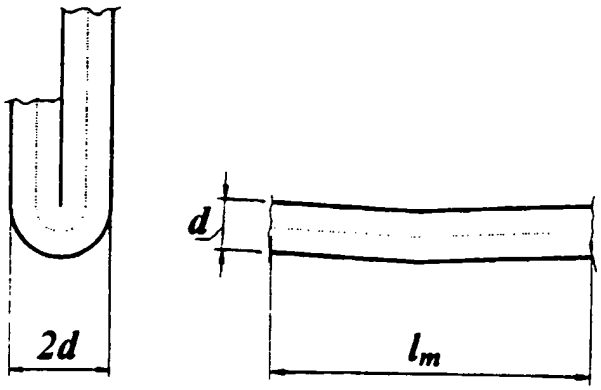


Fig.8

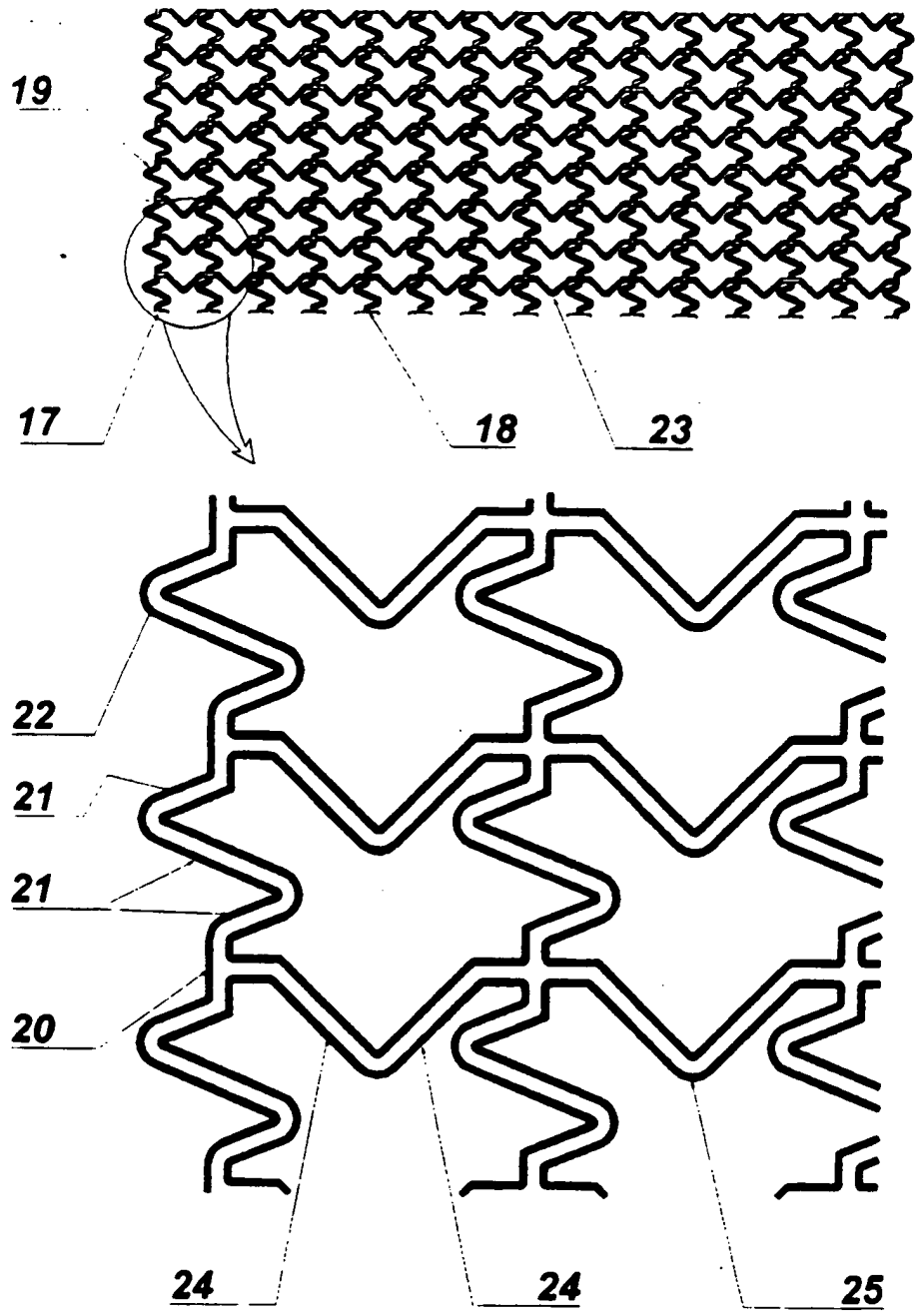


Fig.9

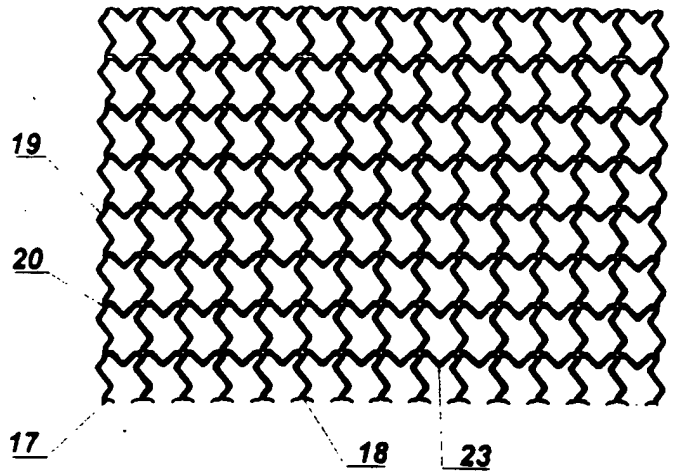


Fig. 10

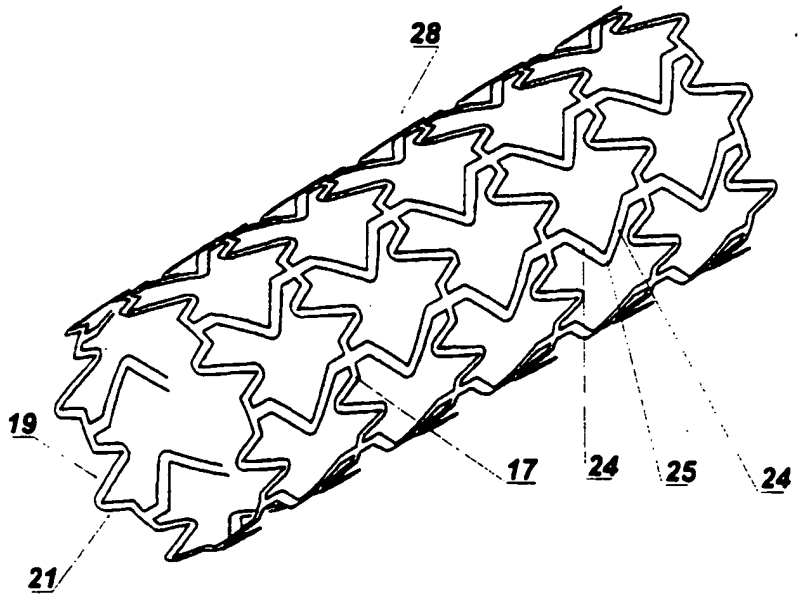


Fig. 11

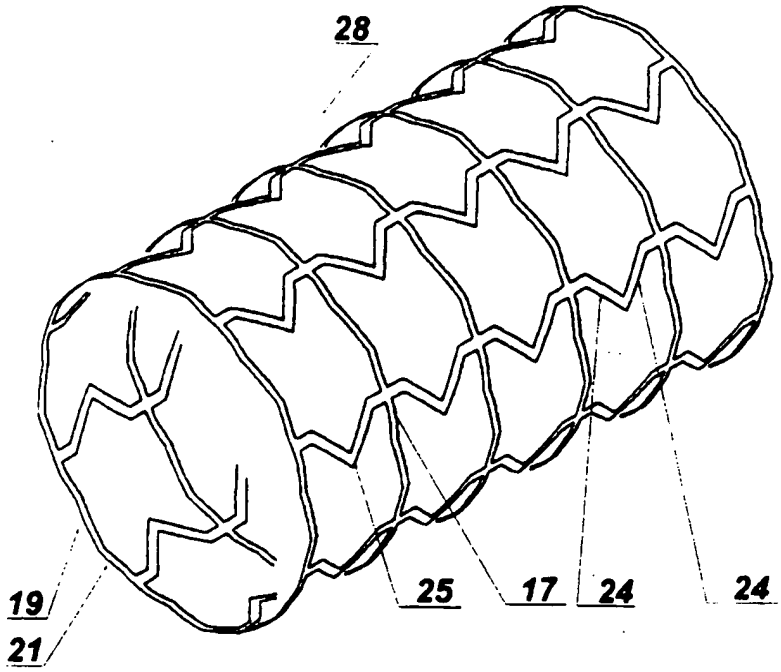


Fig.12

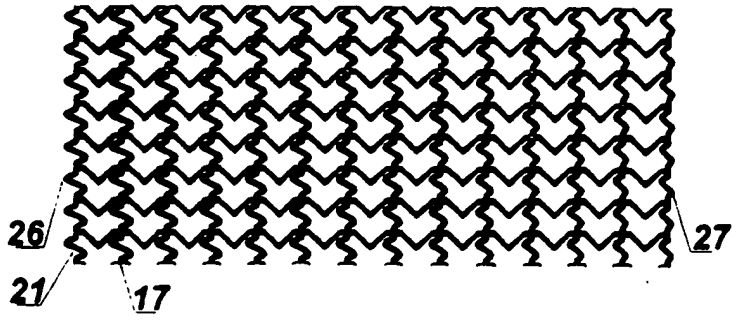


Fig.13

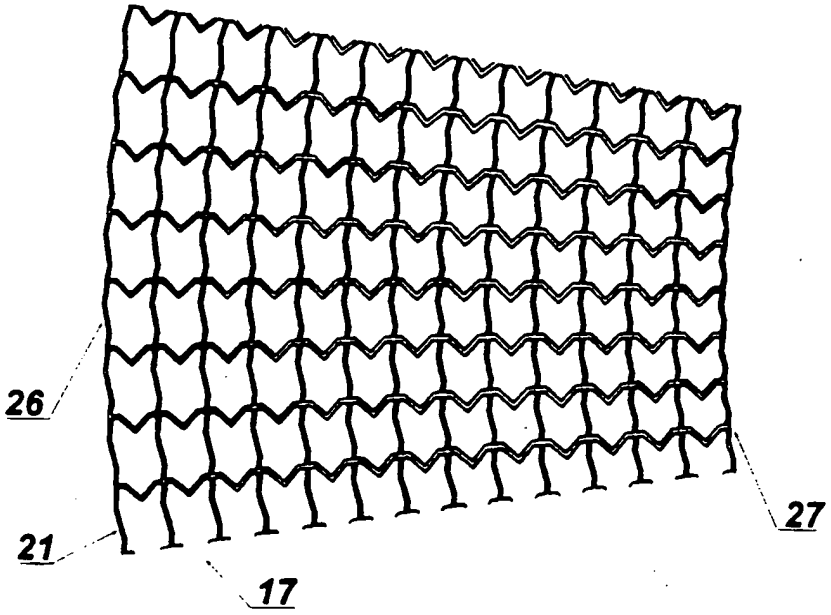


Fig. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL96/00148

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00

US CL :606/194, 195, 198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/194, 195, 198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	US 5,591,197 A (ORTH et al) 07 January 1997, Figs. 1 and 2.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
13 MARCH 1997	27 MAR 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer KEVIN TRUONG Telephone No. (703) 308-3767

Form PCT/ISA/210 (second sheet)(July 1992)*